

REMARKS

In the Office Action dated September 4, 2003, Claims 1-34 are pending. Claims 11-15 are withdrawn from consideration as directed to non-elected subject matter. Claim 3 is objected to for certain alleged informalities. Claims 1-3, 5-10 and 16-34 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enabling support. Claims 3, 4, 16-21 and 24-34 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

This response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Applicants have canceled claims 11-15, drawn to non-elected embodiments. Applicants reserve the right to file one or more divisional applications directed to the subject matter of Claims 11-15.

Applicants have also canceled claims 1-10 and 16-34, rendering all the rejections moot. Applicants reserve the right to file a continuation application to pursue the subject matter of these canceled claims. Withdrawal of the rejections is therefore respectfully requested.

Furthermore, Applicants have added claims 35-38. Claims 35-37 are directed to the χ -conotoxin peptides, MrIA and MrIB. Support for claims 35-37 is found throughout the specification and in original claims 3-4, for example. Claim 38 is directed to a method for the treatment or control of pain by administration of a χ -conotoxin peptide of any one of claims 35-37. Support for claim 38 is also found throughout the specification and in original claim 17, for example. No new matter is introduced by the instant amendment.

Applicants respectfully submit that the Examiner has acknowledged in the Office Action that the specification provides enablement for the conotoxin peptides, MrIA and MrIB, the subject matter of new claims 35-37. Applicants further submit that the subject matter of new

claim 38, i.e., a method for the treatment or control of pain, is also fully enabled by the present specification. In this regard, Applicants respectfully direct the Examiner's attention to the experiments described in Exhibit A, submitted together with the Amendment dated June 11, 2003, which demonstrated that χ -conotoxin (MrIA) produced a dose-dependent antinociceptive effect in a rat model, similar to morphine.

In response, the Examiner has stated in the Office Action that the data on morphine and saline (the control) are not shown in Exhibit A and thus, it is not clear how much effect MrIA had in the treatment of neuropathic pain in the animal model used. During a telephone interview conducted on November 13, 2003, the Examiner suggested to Applicants' representative that further explanation or additional showing should be provided to address this issue.

The experiments referred to in Exhibit A accompanying the Amendment dated June 11, 2003 were conducted by or under the supervision of Dr. Maree T. Smith. Applicants are providing herewith a Declaration of Dr. Maree T. Smith, which provides further details of the experiments showing the therapeutic effects of MrIA.

As described in Paragraph 6 of the Smith Declaration (**Exhibit A** attached hereto) the effects of MrIA, morphine, saline or vehicle (sodium acetate buffer) were assessed in experimental rats having a chronic constriction injury (CCI) of the sciatic nerve. As described in Paragraph 7 of the Smith Declaration and shown in Exhibit 2 attached thereto, MrIA produced dose-dependent relief of tactile allodynia in rats, while neither saline nor vehicle produced any significant antinociception. In addition, morphine produced partial relief of tactile allodynia. Further, as stated by Dr. Smith and indicated by the data in Exhibit 2, it is evident that the antinociceptive effect of MrIA lasts at least as long as the antinociceptive effect of morphine.

Applicants further respectfully submit that as described in the specification, MrIB is a peptide closely related to MrIA and differs from MrIA by only one residue. Thus, those skilled in the art would reasonably expect MrIB to produce a similar antiallodynic effect as MrIA in the treatment or control of pain.

In this regard, Applicants provide a Declaration of Dr. Richard James Lewis (**Exhibit B**), a co-inventor of the present application. As stated in Paragraph 5 of the Declaration, MrIB has a similar ability (2-fold less potent) to enhance the contractile response of rat vas deferens, a simple *in vitro* measure of noradrenaline transporter inhibition. It is Dr. Lewis's opinion that MrIB is expected to produce a similar antiallodynic effect as MrIA, and thus be useful in the treatment of allodynia and related pain.

In view of the foregoing, Applicants respectfully submit that in light of the present teaching, those skilled in the art would be able to make and use the peptides in the treatment or control of pain without undue experimentation. Therefore, the subject matter of claims 35-38 fully satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph.

Accordingly, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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Encls: Exhibit A (with attached Exhibits 1-2)
Exhibit B (with attached Exhibit 1)